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Attachment 14

510(k) Summary Statement for the DermaWave 5000 Combi Max System

1. General Information

Submitter: DermaWave LLC
15693 83rd Lane North
Loxahatchee, FL 33470

Contact Person: Alan Bunting
15693 83rd Lane North
Loxahatchee, FL 33470

Summary Preparation Date: December 4, 2003

2. Names

Device Names: DermaWave 5000 Combi Max System (K040121)

Primary Classification Names:
21 CFR 890.5860, IMG Class 2 Stimulator, Ultrasound
21 CFR 882.5300, IMI Class 2 Diathermy, Ultrasonic
21 CFR 882.5890 84GZJ Class 2 Transcutaneous Electrical Nerve Stimulator (TENS)
21 CFR 882.1320 GXY Class 2 Electrode, Cutaneous
21CFR 882. 5890 LIH Interferential Current Therapy
21 CFR 890.5500 ILY Class 2 Infrared Lamp

3. Predicate Devices

- Chatanooga Group Inc., Vectra 2C & Vectra 4C (K982317)
- Chaatanooga Group Inc. Vectra Pro 2 & Vectra Pro 4 (K982324)
- Dynatronics Corporation, Dynatron 150 Plus Ultrasound (K935728)
- Excel Tech, XL Tek Ultra VM Ultrasound (K001166)
- MedX 1000 Console (K020017)
- MedX LCT 100 Laser Accessory (K032231)
- MedX/Duolight 500 (K032231)
- MedX 600 LED Accessory (K020017)

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4. Product Description

The DermaWave 5000 Combi Max System is comprised of the following main components:

- A system console including software and control electronics.
- A control and display panel.
- Delivery device accessories including patient cables and electrodes, ultrasound cables, soundheads, and infrared heating accessories.

5. Indications for Use

The DermaWave 5000 Combi Max System and the delivery accessories that are used with them are indicated for use in the following:

Stimulation, relaxing, and/or repeatedly contracting muscles by passing electrical currents through electrodes contacting the affected body area in the medical specialties of physical medicine, general and plastic surgery and neurology and/or for use in applying therapeutic deep heat for selected medical conditions such as relief of pain, muscle spasms and joint contractures in the medical specialty of physical medicine.

The indications of the DermaWave 5000 Combi Max System also includes the treatment and relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, maintaining or increasing range of motion, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, symptomatic relief of chronic intractable pain, management of pain associated with post-traumatic or post-operative conditions using electrical stimulation and are indicated for the application of therapeutic deep heat for the treatment of selected medical conditions such as relief of pain, muscle spasms and joint contractures, relief of pain muscle spasms and joint contractures that may be associated with adhesive capsulitis, bursitis with slight calcification, myositis, soft tissue injuries, shortened tendons due to past injuries and scar tissues, relief of chronic and sub-chronic pain and joint contractures resulting from capsular tightness and capsular scarring using ultrasound.

The DermaWave 5000 Combi Max System is also indicated for use in providing topical heating for temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, minor pain and stiffness associated with arthritis.

6. Rationale for Substantial Equivalence

The DermaWave 5000 Combi Max System shares the same general indications for use in physical medicine, general and plastic surgery and neurology applications and share the same or similar basic characteristics and features and, therefore, are substantially equivalent to the:

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- Chatanooga Group Inc., Vectra 2C & Vectra 4C (K982317)
- Chaatanooga Group Inc. Vectra Pro 2 & Vectra Pro 4 (K982324)
- Dynatronics Corporation, Dynatron 150 Plus Ultrasound (K935728)
- Excel Tech, XL Tek Ultra VM Ultrasound (K001166)

The DermaWave 5000 Combi Max System utilizes identical accessories as those produced by MedX Health and share identical indications for use in physical medicine. Further, the MedX accessories comprising the MedX LCT 100 (K032231), MedX Duolight 500 (K032231) and the MedX 600 (K020017) are already cleared. The DermaWave 100 Accessory has almost identical heating characteristics as the MedX line of infrared lamp accessories and falls within the recommended guidelines for such devices in raising the temperature of tissue to no more then 45C in continuous operation over a set time period. The parameters used to achieve the comparative data are based on widely accepted clinical data that require heat lamp devices to elevate the temperature to above 40C and below 45C for a minimum 10 minute period. Comparative temperature charts are included in Section 10 of this submission.

The MedX and Duolight cleared accessories are connected to a control console that provides treatment time information to the user. The control console supplied by MedX and named the MedX 1000/1100 Console, is limited in its control features. The DermaWave 5000 Combi Max System employs sophisticated controls and control systems within system architecture to enhance the safety of the device in applications for which it is used.

7. Safety and Effectiveness Information

Validation documentation and a comparison of the technical characteristics and features were provided to demonstrate that the DermaWave 5000 Combi Max System is safe and effective, when indicated in specific applications in the medical specialties of physical medicine, general and plastic surgery and neurology.

8. Conclusion

The DermaWave 5000 Combi Max System was found to be substantially equivalent to the predicate devices and share similar indications for use and characteristics and functional features and are substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2004

Dermawave, LLC
C/o Mr. Derwyn Reuber
Intertek Testing Services NA, Inc.
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K040121
Trade/Device Name: DermaWave 5000 Combi Max System
Regulation Numbers: 21 CFR §890.5860, 21 CFR §890.5300, 21 CFR §882.5890, 21 CFR §882.1320, 21 CFR §890.5500
Regulation Names: Ultrasound and Muscle Stimulator, Ultrasonic diathermy, Transcutaneous electrical nerve stimulator for pain relief, Cutaneous electrode, Infrared lamp
Regulatory Class: II
Product Codes: IMG, IMI, GZJ, GXY, LIH, ILY
Dated: March 3, 2004
Received: March 5, 2004

Dear Mr. Reuber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040121
Device Name: DermaWave 500 Combi Max
Indications for Use:

Stimulation, relaxing, and/or repeatedly contracting muscles by passing electrical currents through electrodes contacting the affected body area in the medical specialties of physical medicine, general and plastic surgery and neurology and/or for use in applying therapeutic deep heat for selected medical conditions such as relief of pain, muscle spasms and joint contractures in the medical specialty of physical medicine.

The indications of the DermaWave 5000 Combi Max System also include the treatment and relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, maintaining or increasing range of motion, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, symptomatic relief of chronic intractable pain, management of pain associated with post-traumatic or post-operative conditions using electrical stimulation and are indicated for the application of therapeutic deep heat for the treatment of selected medical conditions such as relief of pain, muscle spasms and joint contractures, relief of pain muscle spasms and joint contractures that may be associated with adhesive capsulitis, bursitis with slight calcification, myositis, soft tissue injuries, shortened tendons due to past injuries and scar tissues, relief of chronic and sub-chronic pain and joint contractures resulting from capsular tightness and capsular scarring using ultrasound.

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Mark N Milham

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040121

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)